OTP EDocket No. 000309.00049

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In application of: William J. Carroll

GAU: 3762

Serial No: 10/659,278 Filed: September 11, 2003

Confirmation No. 5691 Examiner: Unknown

For: : Surface electrical stimulation for increasing the quality and quantity of synovial fluid in

ioints

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant(s) wish to disclose the following information.

REF	ERENCES
\boxtimes	The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
	A check is attached in the amount required under 37 CFR §1.17(p).
RELA	ATED CASES
	Attached is a copy of applicant's pending application(s) or issued patent(s) which may be related to the present application. These documents are listed on form PTO-1449, also attached.
	A check is attached in the amount required under 37 CFR §1.17(p).
CER	TIFICATION
	Each item of information contained in this information disclosure statement was cited for the first time in any communication from a foreign patent office in any counterpart foreign application not more than three months prior to the filing of this statement.
	No item of information contained in this information disclosure statement was cited for the first time in any communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37

CFR §1.56(c) more than three months prior to the filing of this statement.

This Information Disclosure Statement is being filed within three months of the filing date of the subject patent application.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits.

PETITION

Applicant(s) hereby request consideration of the attached information. A check is attached in the amount of the Petition fee required under 37 CFR §1.17(i)(1).

DEPOSIT ACCOUNT

Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to deposit account number 23-2185. A duplicate copy of this sheet is enclosed.

Blank Rome LLP 600 New Hampshire Avenue, N.W. Washington, DC 20037

Tel: (202) 772-5800 Fax (202) 572-8398 Customer No.: 27557

Date: August 3, 2004

Respectfully submitted,

Michael C. Greenbaum Attorney of Record Registration No. 28,419 AUG 0 3 2004

Sheet

PTO/SB/08a
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

TRADE Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of

Complete if Known		
Application Number	10/659,278	
Filing Date	September 11, 2003	
First Named Inventor	William J. Carroll	
Art Unit	3762	
Examiner Name	Unknown	
Attorney Docket Number	000309 00049	

			U. S. PATENT DO	DCUMENTS	
Examiner	Cite No.1	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*		Number-Kind Code ^{2 (if known)}	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-6,647,296	11/11/2003	Fischell et al.	
		US-			
		US-			
-		US-			
	•	US-			
		US-			•

34

FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³⁻ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶			
		PCT/US03/37372 International Search Report	11/21/2003	International Rehabilitative Sciences, Inc.	-				
· · · · · · · · · · · · · · · · · · ·									

Examiner	1	Date	
Signature		Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

TO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Su	ubstitute for form 1449A/PTO			Complete if Ki	nown
			u cours	Application Number	10/659,278
	IFORMATION D			Filing Date	September 11, 2003
S	TATEMENT BY	AP	PLICANI	First Named Inventor	William J. Carroll
	(Use as many sheets	as nece	essary)	Art Unit	3762
				Examiner Name	Unknown
Sheet	2	of	4	Attorney Docket Number	000309.00049

	NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²					
		KATAYAMA Y., Deep brain stimulation therapy for involuntary movements, Rinsho Shinkeigaku, 2001/12/01 00:00; 41(12):1079-80, 1 page						
		BENABID AL, et al., Deep btrain stimulation of the corpus luysi (subthalamic nucleus) and other targets in Parkinson's disease. Extension to new indications such as dystonia and epilepsy, J. Neurol. 2001/09/01 00:00; 248 Suppl 3:III37-47, 2 pages						
		ALLERT N., et al., Effects of bilateral pallidal or subthalamic stimulation on gait in advanced Parkinson's disease, Mov Disord. 2001/11/01 00:00; 16(6):1076-85, 2 pages						
		UTTI RJ, et al., Extended Follow-up of Unilateral Deep Brain Stimulation for Tremor, Deep brain stimulation remains an effective treatment for tremor for at least 3 years, according to this article, P03.1123; A220-221						
		OBWEGESER AA, et al., Quantitative and qualitative outcome measures after thalamic deep brain stimulation to treat disabling tremors, Neurosurgery, 48(2): 274-81, discussion 281-4 2001, 2-page Article						
		OBWEGESER AA, et al., Simultaneous thalamic deep brain stimulation and implanatable cardioverter-defibrillator, Mayo Clin Proc, 76(1): 87-9, 2001, 2-page Abstract						
		OBWEGESER AA, et al., Thalamic stimulation for the treatment of midline tremors in essential tremor patients, Nekurology, 54(12): 2342-4 2000, 2-page Abstract						
		OH MY, et al., Deep brain stimulator electrodes used for lesioning: proof of principle, Neurosurgery, 2001/08/01 00:00; 49(2): 363-7; discussion 367-9, 2-page Article						
		RACETTE BA, et al., Thalamic stimulation for primary writing tremor, J Neurol. 2001/05/01 00:00; 248(5): 380-2, 2-page Report						
		ROCCHI L, et al, Effects of deep brain stimulation and levodopa on postural sway in Parkinson's disease, J. Neuro Neurosurg Psychiatry, 2002 Sep; 73(3):267-74, 2-page Article						

		*	
Examiner Signature	Date Considered		

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 06/30/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Substitute for form 1449A/PTO			Complete if Known				
		D		Application Number	10/659,278			
	INFORMATION			Filing Date	September 11, 2003			
	STATEMENT B	YAP	PLICANI	First Named Inventor	William J. Carroll			
	(Use as many sheet	s as nece	ssary)	Art Unit	3762			
				Examiner Name	Unknown			
Shee	t 3	of	4	Attorney Docket Number	000309.00049			

NON PATENT LITERATURE DOCUMENTS								
Examiner nitials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²					
		NASSER JA, et al, Deep brain stimulation of VIM thalamic nucleus for tremor control, Arq Neuropsiquiatr. 2002 Jun; 60(2-B):429-34, 1-page Article						
		RACETTE BA, et al., Ipsilateral thalamic stimulation after thalamotomy for essential tremor. A case report., Stereotact Funct Neurosurg. 2000/01/01 00:00; 75(4): 155-9, 2-page Article						
		RERZAI AR, et al., Neurostimulation systems for deep brain stimulation: in vitro evaluation of magnetic resonance imaging-related heating at 1.5 tesla, J Magn Reson Imaging, 2002/03/01 00:00; 15(3):241-50, 2-page Article						
		MAYA PINES, New Imaging Techniques That Show the Brain at Work: Brain Scans That Spy on the Senses, Seeing, Hearing, and Smelling the World, A Report from the Howard Hughes Medical Institute, 2-page Article						
<u>-</u> -		MAYA PINES, New Imaging Techniques That Show the Brain at Work: The Next Generation of Brain Scans, Seeing, Hearing, and Smelling the World, A Report from the Howard Hughes Medical Institute, 2-page Article						
		Oregon Imaging Article, P.E.T. Scan - Patient Information, 2 page Article						
		CIGNA CORPORATION, Positron Emission Tomography (PET) Scans - Medical Coverage, All States, 1999, 7-page Article						
		REZAI AR, et al., Neurostimulation systems for deep brain stimulation: in vitro evaluation of magnetic resonance imaging-related heating at 1.5 tesla, J magn Reson Imaging, 2002/03/01 00:00; 15(3):241-50, 2-page Article						
,		MOBILE PET SYSTEMS, INC., Clinical Applications, 5-pages						
		NEUROLOGICAL ASSOCIATES, INC., Deep Brain Stimulation, West Virginia, 6-page Article						

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

TO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Substitute for form 1449A/PTO		Complete if Known			
			Application Number	10/659,278		
-	••• ••••	DISCLOSURE	Filing Date	September 11, 2003		
•	SIAIEMENIB	Y APPLICANT	First Named Inventor	William J. Carroll		
	(Use as many she	ets as necessary)	Art Unit	3762		
			Examiner Name	Unknown		
Sheet	4	4	Attorney Docket Number	000309.00049		

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²		
		MOHAMED A. HAMZA, M.D., et al., Effect of the Duration of Electrical Stimulation on the Analgesic Response in Patients with Low Back Pain, Anesthesiology, December 1999, pp. 1622-1627, Vol. 91, No. 6			
		EL-SAYED A. GHONAME, M.D., et al., The Effect of Stimulus Frequency on the Analgesic Response to Percutaneous Electrical Nerve Stimulation in Patients with Chronic Low Back Pain, Anesthesia & Analgesia, April 1999, pp. 841-846, Vol. 88, No. 4			
		RICHARD E. SEROUSSI, MD, et al., Effectiveness of Percutaneous Neuromodulation Therapy for Patients with Chronic and Severe Low Back Pain, 2003, pp. 22-30, Vol. 3, Issue 1, Pain Practice			
		EL-SAYED A. CHONAME, MD, et al., Percutaneous Electrical Nerve Stimulation for Low Back Pain, JAMA, March 3, 1999, Vol. 281, No. 9			
		ANDREW J. ROBINSON, Clinical Electrophysiology, Electrotherapy and Electrophysiologic Testing, pp. cover, 285, 288-290, Second Edition, Williams & Wilkins			
		M.I. JOHNSON, et al., An in-depth study of long-term users of transcutaneous electrical nerve stimulation (TENS). Implications for clinical use of TENS, Pain 41, 1991, pp. 221-229, Elsevier Science Publishers B.V.			
		J.S. HAN, et al., Effect ov low- and high-frequency TENS on Met-enkephalin-Arg-Phe and dynorphin A immunoreactivity in human lumbar CSF, 1991, pp. 295-298, Elsevier Science Publishers B.V.			
		ROGER M. NELSON, et al., Clinical Electrotherapy, third edition, Appleton & Lange, Stamford, Connecticut			
		Vertis Percutaneous Neuromodulation Therapy (PNT), Peer Review Network, Inc., PRN Newsletter, November 2002, Vol. 9, No. 6., pp. 1-5			
		PRIYA GOPALKRISHNAN, MS, et al., Effect of Varying Frequency, Intensity, and Pulse Duration of Transcutaneous Electrical Nerve Stimulation on Primary Hyperalgesia in Inflamed Rats, Arch Phys Med Rehabil, Vol. 81, July 2000, pp. 984-990			
		M.I. JOHNSON, et al., Analgesic effects of different frequencies of transcutaneous electrical nerve stimulation on cold-induced pain in normal subjects, Pain 39 (1989), pp. 231-236, Elsevier Science Publishers B.V.			
-		SERGE MARCHAND, M.Sc., et al., Modulation of Heat Pain Perception by High Frequency Transcutaneous Electrical Nerve Stimulation (TENS), The Clinical Journal of Pain, Vol. 7, No. 2, 1991, pp. 122-129			

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.